The most serious adverse reactions reported with dicyclomine hydrochloride include cardiovascular and central nervous system symptoms [see Warnings and Precautions (5.2, 5.3)]. 6.1 Clinical Trials Experience Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials

f a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed In practice. The data described below reflect exposure in controlled clinical trials involving over 100 patients treated for functional bowel/irritable bowel syndrome with dicyclomine hydrochloride at initial doses of 160 mg daily (40 mg four times a day). In these trials most of the side effects were typically anticholinergic in nature and were reported by 61% of the patients. Table 1 presents adverse reactions (*Med-DRA 13.0* preferred terms) by decreasing order of frequency in a side-by-side comparison with placebo. Table 1: Adverse Reactions Experienced in Controlled Clinical Trials with Decreasing Order of Frequence

## MedDRA Preferred Term

y Mouth
zziness
sion blurred
lusea
omnolence
thenia
ervousness

Nine percent (9%) of patients were discontinued from dicvclomine hydrochloride because of one or more of these side teffects (compared with 2% in the placebo group). In 41% of the patients with side effects, side effects disappeared or were tolerated at the 160 mg daily dose without reduction. A dose reduction from 160 mg daily to an average daily dose of 90 Clinical studies of dicvo mg was required in 46% of the patients with side effects who then continued to experience a favorable clinical response their side effects either disappeared or were tolerated.

6.2 Postmarketing Experience The following adverse reactions, presented by system organ class in alphabetical order, have been identified during pos approval use of dicyclomine. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Cardiac disorders: palpitations, tachyarrhythmias

Eye disorders: cycloplegia, mydriasis, vision blurred Gastrointestinal disorders: abdominal distension, abdominal pain, constipation, dry mouth, dyspepsia, nausea,

- vomitina • General disorders and administration site conditions: fatigue, malais
- Immune System Disorders: drug hypersensitivity including face edema, angioedema, anaphylactic shock
- Nervous system disorders: dizziness, headache, somnolence, syncope

Name

Date



- -- DRUG INTERACTIONS --- Antiglaucoma agents: anticholinergics antagonize antiglaucoma agents and may increase intraoccular pressure (7) <u>Anticholinergic agents</u>: may affect the gastrointestinal absorption of various drugs; may also increase certain actions or side effects of other anticholinergic drugs (7)
- Antacids: interfere with the absorption of anticholinergic agents (7)

HIGHLIGHTS OF PRESCRIBING INFORMATION

Initial U.S. Approval: 1950

Unstable cardiovas

and/or in patients dicyclomine (5.3)

ervousness (6)

Glaucoma (4)

DICYCLOMINE HYDROCHLORIDE injection, for intramuscular use

Warnings and Precautions, Peripheral and Central Nervous System (5.3)

These highlights do not include all the information needed to use DICYCLOMINE HYDROCHLORIDE INJECTION safely and effectively. See full prescribing information for DICYCLOMINE HYDROCHLORIDE INJECTION.

---RECENT MAJOR CHANGES ----

- Pediatric Use: Safety and effectiveness not established (8.4)
- Hepatic and renal impairment: caution must be taken with patients with significantly impaired hepatic and renal function (8.6)

## See 17 for PATIENT COUNSELING INFORMATION

FULL PRESCRIBING INFORMATION: CONTENTS\*

- INDICATIONS AND USAGE DOSAGE AND ADMINISTRATION
- ntramuscular Dosage and Ac 2.3 Preparation for Intramuscular Administration DOSAGE FORMS AND STRENGTHS
- CONTRAINDICATIONS WARNINGS AND PRECAUTIONS
- Inadvertent Intravenous Administration
- Cardiovascular Conditions Peripheral and Central Nervous System
- Myasthenia Gravis
- Intestinal Obstruction 5.6
- Toxic Dilatation of Intestinemegacolor
- Ulcerative Colitis Prostatic Hypertrophy
- Hepatic and Renal Disease
- 5.10 Geriatric Population

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# 78-9000-SNI

Injection, USP Dicyclomine Hydrochloride

Dicyclomine Hydrochloride Injection, USP





Item: INS-0006-B4 Eval: X3731585

*[see Adverse Reactions (6)].* In the presence of high environmental temperature heat prostration can occur with drug use (fever and heat stroke due to decreased sweating). It should also be used cautiously in patients with fever. If symptoms occur, the drug should be discontinued and supportive measures instituted. Because of the inhibitory effect on muscarinic receptors within the autonomic neuropathy. Central nervous system, caution should be taken in patients with autonomic neuropathy. Central nervous system, cutton should be taken in patients with autonomic neuropathy. Central nervous system, cutton should be taken in patients with autonomic neuropathy. Central nervous system (CNS) signs and symptoms include confusional state, disorientation, amnesia, hallucination, disperioritat affect. Psychosis and delirium have been reported in sensitive individuals (such as elderly patients and/or in patients with discontinued on drug.



ENSE INCRV TIONS Clinical Trials Experience Postmarketing Experience Adverse Reactions Reported with Similar Drugs with Anticholinergic/Antispasmodic Action

ADVERSE REACTIONS

DRUG INTERACTIONS

07/2012

- 17.1 Inadvertent Intravenous Administration
  17.2 Use in Infants
  17.3 Use in Nursing Mothers
  17.4 Peripheral and Central Nervous System

## FULL PRESCRIBING INFORMATION

Dicyclomine Hydrochloride Injection, USP is indicated for the treatment of patients with functional bowel/irritable bowel

Dosage must be adjusted to individual patient need

Intramuscular Dicyclomine Injection must be administered via intramuscular route only. Do not administer by any other

The recommended intramuscular dose is 10 mg to 20 mg four times a day [see Clinical Pharmacology (12)]. The intramuscular injection is to be used only for 1 or 2 days when the patient cannot take oral medication. Intramuscular injection is about twice as bioavailable as oral dosage forms.

### Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration,

whenever solution and container permit. Aspirate the syringe before injecting to avoid intravascular injection, since thrombosis may occur if the drug is inadvertently injected intravascularly

CONTRAINDICATIONS

cyclomine is contraindicated in infants less than 6 months of age [see Use in Specific Populations (8.4)], nursing others [see Use in Specific Populations (8.3)], and in patients with: unstable cardiovascular status in acute hemorrhage myasthenia gravis [see Warnings and Precautions (5.4)] glaucoma [see Adverse Reactions (6.3) and Drug Interactions (7.1)] obstructive uropathy [see Warnings and Precautions (5.8)] obstructive disease of the gastrointestinal tract [see Warnings and Precautions (5.5)] severe ulcerative colitis [see Warnings and Precautions (5.7)] reflux esonabaditis

reflux esophagitis

### WARNINGS AND PRECAUTIONS

5.1 Inadvertent Intravenous Administration

Dicyclomine hydrochloride solution is for intramuscular administration only. Do not administer by any other route Inadvertent intravenous administration may result in thrombosis, thrombophlebitis, and injection site reactions such as

Revised: 7/2019 5.2 Cardiovascular Conditions

pain, edema, skin color change, and reflex sympathetic dystrophy syndrome [see Adverse Reactions (6.2)]. Dicyclomine hydrochloride needs to be used with caution in conditions characterized by tachyarrhythmia such as

thyrotoxicosis, congestive heart failure and in cardiac surgery, where they may further accelerate the heart rate. Investigate any tachycardia before administration of dicyclomine hydrochloride. Care is required in patients with coronary heart disease, as ischemia and infarction may be worsened, and in patients with hypertension [see Adverse Reactions (6.3)]. 5.3 Peripheral and Central Nervous System

The peripheral effects of dicyclomine hydrochloride are a consequence of their inhibitory effect on muscarinic receptors of the autonomic nervous system. They include dryness of the mouth with difficulty in swallowing and talking, thirst, reduced bronchial secretions, dilatation of the pupils (mydriasis) with loss of accommodation (cycloplegia) and photophobia, flushing and dryness of the skin, transient bradycardia followed by tachycardia, with palpitations and arrhythmias, and difficulty in micturition, as well as reduction in the tone and motility of the gastrointestinal tract leading to constipation

discontinuation of the drug.

Dicyclomine hydrochloride may produce drowsiness, dizziness or blurred vision. The patient should be warned not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery or performing hazardous work while taking dicyclomine hydrochloride. 6.3 Adverse Reactions Reported with Similar Drugs with Anticholinergic/Antispast Gastrointestinal: anorexia Central Nervous System: tinoling, numbness, dyskinesia, speech disturbance, insomnia

### 5.4 Myasthenia Gravis

With overdosage, a curare-like action may occur (i.e., neuromuscular blockade leading to muscular weakness and possible paralysis). It should not be given to patients with myasthenia gravis except to reduce adverse muscarinic effects of an anticholinesterase [see Contraindications (4)].

#### 5.5 Intestinal Obstruction

5.6 Toxic Dilatation of Intestinemegacolon

with Salmonella dysente

5.7 Ulcerative Colitis

nitourinary: urinary hesitancy, urinary retention in patients with prostatic hypertrophy

muscular weakness and possible paralysis)

Central Nervous System: tingling, numbness, dyskinesia, speech disturbance, insor

Dermatologic/Allergic: urticaria, itching, and other dermal manifestations

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with this drug would be inappropriate and possibly harmful [see Contraindications (4)]. Respiratory: apnea

Rarely development of Ogilvie's syndrome (colonic pseudo-obstruction) has been reported. Ogilvie's syndrome is a clinical disorder with signs, symptoms, and radiographic appearance of an acute large bowel obstruction but with no evidence of distal colonic obstruction. Other: decreased sweating, sneezing, throat congestion, impotence. With the injectable form, there may be temporary sensation of light-headedness. Some local irritation and focal coagulation necrosis may occur following the intramuscula injection of dicyclomine hydrochloride.

Peripheral Nervous System: With overdosage, a curare-like action may occur (i.e., neuromuscular blockade leading to

DRUG INTERACTIONS

### Toxic dilatation of intestine and intestinal perforation is possible when anticholinergic agents are administered in patients 7.1 Antiglaucoma Agents

Anticholinergics antagonize the effects of antiglaucoma agents. Anticholinergic drugs in the presence of increased intraocular pressure may be hazardous when taken concurrently with agents such as corticosteroids. Use of dicyclomine hydrochloride in patients with glaucoma is not recommended [see Contraindications (4)]. Caution should be taken in patients with ulcerative colitis. Large doses may suppress intestinal motility to the point

## of producing a paralytic ileus and the use of this drug may precipitate or aggravate the serious complication of toxic megacolon [see Adverse Reactions (6.3)]. Dicyclomine hydrochloride is contraindicated in patients with severe ulcerative The following agents may increase order agents.

The following agents may increase certain actions or side effects of anticholinergic drugs including dicyclomine hydrochloride: amantadine, antiarrhythmic agents of Class I (e.g., quinidine), antihistamines, antipsychotic agents (e.g., phenothiazines), benzodiazepines, MAO inhibitors, narcotic analgesics (e.g., meperidine), nitrates and nitrites, sympathomimetic agents, tricyclic antidepressants, and other drugs having anticholinergic activity.

#### 7.3 Other Gastrointestinal Motility Drugs

Interaction with other gastrointestinal motility drugs may antagonize the effects of drugs that alter gastrointestinal motility, such as metoclopramid

#### 7.4 Effect of Antacids

Because antacids may interfere with the absorption of anticholinergic agents including dicyclomine hydrochloride, simultaneous use of these drugs should be avoided.

### 7.5 Effect on Absorption of Other Drugs

Anticholinergic agents may affect gastrointestinal absorption of various drugs by affecting on gastrointestinal motility, such as slowly dissolving dosage forms of digoxin; increased serum digoxin concentration may result.

### 7.6 Effect on Gastric Acid Secretion

The inhibiting effects of anticholinergic drugs on gastric hydrochloric acid secretion are antagonized by agents used to treat achlorhydria and those used to test gastric secretion.

8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

Adequate and well-controlled studies have not been conducted with dicyclomine hydrochloride in pregnant women at the recommended doses of 80 to 160 mg/day. However, epidemiologic studies did not show an increased risk of structural malformations among babies born to women who took products containing dicyclomine hydrochloride at doses up to 40 mg/day during the first trimester of pregnancy. Reproduction studies have been performed in rats and rabbits at doses up to 33 times the maximum recommended human dose based on 160 mg/day (3 mg/kg) and have revealed on o evidence of harm to the fetus due to dicyclomine. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

### 8.3 Nursing Mothers

Dicyclomine hydrochloride is contraindicated in women who are breastfeeding. Dicyclomine hydrochloride is excreted in human milk. Because of the potential for serious adverse reactions in breast-fed infants from dicyclomine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother [see Use in Specific Populations (8.4)].

### 8.4 Pediatric Use

Placeho %

Safety and effectiveness in pediatric patients have not been established.

Dicyclomine hydrochloride is contraindicated in infants less than 6 months of age *Isee Contraindications (4)*]. There are published cases reporting that the administration of dicyclomine hydrochloride to infants has been followed by serious respiratory symptoms (dyspnea, shortness of breath, breathlessness, respiratory collapse, apnea and asphyxia), seizures, syncope, pulse rate fluctuations, muscular hypotonia, and coma, and death, however; no causal relationship has been established

Clinical studies of dicyclomine hydrochloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range in adults, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

### 8.6 Renal Impairment

Effects of renal impairment on PK, safety and efficacy of dicyclomine hydrochloride have not been studied. Dicyclomine hydrochloride drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Dicyclomine hydrochloride should be administered with caution in patients with renal impairment.

### 8.7 Hepatic Impairment

Effects of renal impairment on PK, safety and efficacy of dicyclomine have not been studied. Dicyclomine hydrochloride should be administered with caution in patients with hepatic impairment.

Psychiatric disorders: As with the other anti-cholinergic drugs, cases of delirium or symptoms of delirium such as annesia (or transient global annesia), agitation, confusional state, delusion, disorientation, hallucination (including visual hallucination) as well as mania, mood altered and pseudodementia, have been reported with the use of Dicyclomine. Nervousness and insomnia have also been reported. In case of an overdose, patients should contact a physician, poison control center (1-800-222-1222), or emergency room The signs and symptoms is not constant a physician, poison control center (1-60-222-1222), or energiency form, the signs and symptoms of overdosage include: headache; nausea; vomiting; futured vision; ditated pupils; hot, dry skir; dizziness; dryness of the mouth; difficulty in swallowing; and CNS stimulation including convulsion. A curare-like action may occur (i.e., neuromuscular blockade leading to muscular weakness and possible paralysis). One reported event included a 37 year old who reported numbness on the left side, cold fingertips, blurred vision, abdominal and flank pain, decreased appetite, dry mouth, and nervousness following ingestion of 320 mg daily (four 20 mg tablets four times daily). These events resolved after discontinuing the dicyclomine.

The acute oral LD50 of the drug is 625 mg/kg in mice.

The amount of drug in a single dose that is ordinarily associated with symptoms of overdosage or that is likely to be lifethreatening, has not been defined. The maximum human oral dose recorded was 600 mg by mouth in a 10 month old child and approximately 1500 mg in an adult, each of whom survived. In three of the infants who died following administration

Dicyclomine Hydrochloride (40 mg four times a day)

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of dicyclomine hydrochloride [see Warnings and Precautions (5.1)], the blood concentrations of drug were 200, 220, and 505 ng/mL.

It is not known if dicyclomine hydrochloride is dialyzable. Treatment should consist of gastric lavage, emetics, and activated charcoal. Sedatives (e.g., short-acting barbiturates, benzodiazepines) may be used for management of overt signs of excitement. If indicated, an appropriate parenteral cholinergic agent may be used as an antidote.

### 11 DESCRIPTION

Dicyclomine is an antispasmodic and anticholinergic (antimuscarinic) agent available in the following dosage form: Dicyclomine Hydrochloride Injection, USP is a sterile, pyrogen-free, aqueous solution for intramuscular injection (NOT FOR INTRAVENOUS USE). Each mL contains 10 mg dicyclomine hydrochloride USP in sterile water for injection, made

sotonic with sodium chloride. Dicyclomine hydrochloride is [bicyclohexyl]-1-carboxylic acid, 2-(diethylamino) ethyl ester, hydrochloride, with a molecular formula of  $C_{19}H_{35}NO_{2}$ . HCI and the following structural formula:



PETERSON Camber Pharmaceutica Piscataway, NJ 08854

Manufactured for

centicals Inc.

INS-0006 R4

сн<sub>2</sub>-сн<sub>3</sub> • нсі 0 II C-O-CH<sub>2</sub>-CH<sub>2</sub>-N CH<sub>2</sub>-CH<sub>3</sub>

Molecular weight: 345.95

Dicyclomine hydrochloride occurs as a fine, white, crystalline, practically odorless powder with a bitter taste. It is soluble in water, freely soluble in alcohol and chloroform, and very slightly soluble in ether.

## 12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dicyclomine relieves smooth muscle spasm of the gastrointestinal tract. Animal studies indicate that this action is achieved via a dual mechanism:

- a specific anticholinergic effect (antimuscarinic) at the acetylcholine-receptor sites with approximately 1/8 the
  milligram potency of atropine (in vitro, guinea pig ileum); and
- a direct effect upon smooth muscle (musculotropic) as evidenced by dicyclomine's antagonism of bradykinin- and histamine-induced spasms of the isolated guinea pig ileum.

Atropine did not affect responses to these two agonists. In vivo studies in cats and dogs showed dicyclomine to be equally potent against acetylcholine (ACh)- or barium chloride (BaCl2)-induced intestinal spasm while atropine was at least 200 times more potent against effects of ACh than BaCl2. Tests for mydriatic effects in mice showed that dicyclomine was approximately 1/500 as potent as atropine; antisialagogue tests in rabbits showed dicyclomine to be 1/300 as potent as atropine.

### 12.2 Pharmacodynamics

Dicyclomine hydrochloride can inhibit the secretion of saliva and sweat, decrease gastrointestinal secretions and motility, cause drowsiness, dilate the pupils, increase heart rate, and depress motor function.

## 12.3 Pharmacokinetics

Absorption and Distribution

In man, dicyclomine is rapidly absorbed after oral administration, reaching peak values within 60 to 90 minutes. Mean volume of distribution for a 20 mg oral dose is approximately 3.65 L/kg suggesting extensive distribution in tissues.

Elimination The metabolism of dicyclomine was not studied. The principal route of excretion is via the urine (79.5% of the dose). Excretion also occurs in the feces, but to a lesser extent (8.4%). Mean half-life of plasma elimination in one study was determined to be approximately 1.3 hours when plasma concentrations were measured for 9 hours after a single dose. In subsequent studies, plasma concentrations were followed for up to 24 hours after a single dose, showing a secondary phase of elimination with a somewhat longer half-life.

### 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of dicyclomine. In studies in rats at doses of up to 100 mg/kg/day, dicyclomine produced no deleterious effects on breeding, conception, or parturition.

### 14 CLINICAL STUDIES

In controlled clinical trials involving over 100 patients who received drug, 82% of patients treated for functional bowel/ irritable bowel syndrome with dicyclomine hydrochloride at initial doses of 160 mg daily (40 mg four times daily) demonstrated a favorable clinical response compared with 55% treated with placebo (p<0.05).

#### 16 HOW SUPPLIED/STORAGE AND HANDLING

Dicyclomine Hydrochloride Injection, USP, 20 mg/2 mL (10 mg/mL), (for Intramuscular use only, NOT FOR Intravenous USE) is supplied as follows:

NDC 31722-963-32: 5 x 2 mL Single Dose Vials

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from freezing.

17 PATIENT COUNSELING INFORMATION 17.1 Inadvertent Intravenous Administration

Dicyclomine injection is for intramuscular administration only. Do not administer by any other route. Inadvertent administration may result in thrombosis or thrombophlebitis, and injection site reactions such as pain, edema, skin color change and even reflex sympathetic dystrophy syndrome [see Adverse Reactions (6.2)].

### 17.2 Use in Infants

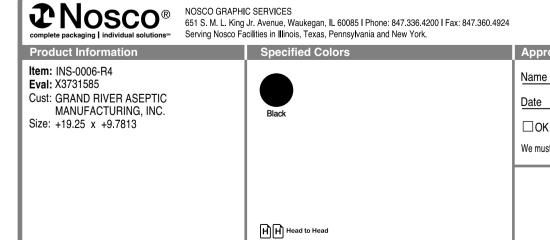
Inform parents and caregivers not to administer dicyclomine in infants less than 6 months of age [see Use in Specific Populations (8.4)].

### 17.3 Use in Nursing Mothers

Advise lactating women that dicyclomine should not be used while breastfeeding their infants [see Use in Specific Populations (8.3, 8.4)].

### 17.4 Peripheral and Central Nervous System

In the presence of a high environmental temperature, heat prostration can occur with dicyclomine hydrochloride use (fever and heat stroke due to decreased sweating). If symptoms occur, the drug should be discontinued and a physician contacted. Dicyclomine hydrochloride may produce drowsiness or blurred vision. The patient should be warned not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery or to perform hazardous work while taking dicyclomine [see Warnings and Precautions (5.3)].



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	Report Summary
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99	99	99	88	99	99	90	99	99	98	99	96	95	99	99	91	97	99
99	99	85	97	84	99	91	99	94	99	96	99	99	99	83	99	94	99
99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99



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	Report Summary
Data	INS-0006-R4
Unicode Data	INS-0006-R4
Symbology	DataMatrix
Company Name	Nosco Inc

Verification Grades								
Standard	Grade	Aperture	Wavelength	Lighting	Formal Grade			
ISO29158 (AIM-DPM)	A (4.0)	15	660	45Q	DPM 4.0/15/660/45Q			

In	nage				G	eneral Characteristi	CS	
	Sall P	1. 11.	1 1 1 1 1 2		Matrix Size	16x16 (Data: 14x14)		
					Horizontal BWG	0%		
	-			Vertical BWG	2%			
			ESERCE R	Encoded characters	11			
	-		Saleria	12974	Total Codewords	24		
	-	- <b>-</b> -	1000000000		Data Codewords	12		
Statistics of Barbs		<b>—</b>	STOR STOR	1.44	Error Correction Budget	12		
	_		1912 R. 17. 19	05319	Errors Corrected	0		
			11-1-78 S	1250	Error Capacity Used	0		
Contraction of Contra	-	_	FASSING ST	-0042	Error Correction Type	ECC 200		
		1.1	C. S. S. S. S. S.	23313	Image	Black on white		
		1	1000		Nominal X Dim	18.2 mil		
		-	H. C. Mark	No. St.	Contrast Uniformity	86 at module(11,2)		
			Contraction of the	1997	MRD	80% (86% - 6%)		
			1990 P. S. M. S.		Stability	Stability 81%		
					073 078 083 045 048	ASCII Values	052	
ISO 29158 Qu	ality P	arame	eters		D	ata Matrix Codeword	ls	
1. Unused Error Correction (UEC)	100%	А		PASS		E 53 35 81 FB 93 A2		
2. Cell Contrast (CC)	89%	А	RI/Rd (100/10)	PASS	46 5A 08 1E 8F			
3a. Cell Modulation (CMOD)		А		PASS	*=Fixed by Error Correction	on		
3b. Reflectance Margin (RM)		А		PASS	,			
4. Axial Nonuniformity (ANU)	0%	Α		PASS		Encodation Analysis	; ;	
5. Grid Nonuniformity (GNU)	3%	Α		PASS	Codeword	Mode	Result	
6. Fixed Pattern Damage (FPD)	4.0	Α		PASS	4A	ASCII		
7. Left 'L' Side (LLS)		А		PASS	4F	ASCII		
8. Bottom 'L' Side (BLS)		А		PASS	54	ASCII		
					17.1	/10011	-	

3b. Reflectance Margin (RM)		А	PASS	
4. Axial Nonuniformity (ANU)	0%	А	PASS	
5. Grid Nonuniformity (GNU)	3%	А	PASS	Codeword
6. Fixed Pattern Damage (FPD)	4.0	А	PASS	
7. Left 'L' Side (LLS)		Α	PASS	4F
8. Bottom 'L' Side (BLS)		Α	PASS	54
9. Left Quiet Zone (LQZ)		Α	PASS	
10. Bottom Quiet Zone (BQZ)		Α	PASS	
11. Top Quiet Zone (TQZ)		Α	PASS	88
12. Right Quiet Zone (RQZ)		А	PASS	2E
13. Top Transition Ratio (TTR)	0%	Α	PASS	
14. Right Transition Ratio (RTR)	0%	Α	PASS	
15. Top Clock Track (TCT)		Α	PASS	
16. Right Clock Track (RCT)		А	PASS	
17. Distributed Damage Grade (DDG)	4.0	А	PASS	93
18. DECODE		А	PASS	A2, 0A, D0, 91, F0, CE DD, 46, 5A, 08, 1E, 8F
19. Minimum Reflectance (MR)	83%	А	PASS	DD, 40, 5A, 00, TL, 01

Encodation Analysis									
Codeword	Mode	Result							
4A	ASCII	1							
4F	ASCII	Ν							
54	ASCII	S							
2E	ASCII	-							
82	ASCII	00							
88	ASCII	06							
2E	ASCII	-							
53	ASCII	R							
35	ASCII	4							
81	ASCII	ASCII PAD							
FB	ASCII	ASCII PAD							
93	ASCII	ASCII PAD							
A2, 0A, D0, 91, F0, CB, DD, 46, 5A, 08, 1E, 8F	ECC								



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Modulation Values																	
99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
99	97	99	99	96	99	99	99	98	99	97	96	99	99	99	96	99	99
99	99	97	99	99	93	99	99	98	99	99	94	99	99	99	99	96	99
99	99	97	93	99	99	97	99	99	90	98	95	99	99	99	97	99	99
99	98	99	97	99	94	99	96	99	96	94	96	99	99	99	99	98	99
99	99	99	99	94	95	99	95	94	93	95	99	99	99	99	96	99	99
99	98	95	99	99	99	99	99	90	99	99	91	99	99	99	99	99	99
99	99	99	99	99	96	99	99	99	99	96	99	99	99	99	99	99	99
99	99	96	99	96	99	97	99	99	95	96	99	99	99	99	99	99	99
99	98	99	99	99	99	98	99	99	99	99	99	99	99	99	97	99	99
99	99	96	99	99	99	99	99	99	99	99	99	99	99	99	99	96	99
99	97	99	99	90	99	99	91	99	99	99	99	99	99	99	99	93	99
99	96	99	86	94	95	91	99	98	99	98	99	99	97	99	99	99	99
99	99	91	99	99	90	99	99	97	99	99	93	99	99	99	98	99	99
99	99	99	87	99	99	91	99	99	99	99	98	97	99	99	94	99	99
99	99	94	99	88	99	90	99	94	97	95	99	99	99	87	99	95	99
99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
99	99	99	99	99	99	99	99	99	99	99	99	99	99	98	99	99	99